REMARKS/ARGUMENTS

Upon entry of this Amendment, claims 8 and 33-43 are pending in this application and are presented for examination. Claim 1-7 and 9-11 were previously canceled, and withdrawn claims 12-32 have now been canceled without prejudice to future prosecution.

In an earnest effort to expedite prosecution, Applicants have amended claim 8 to recite an imiquimod composition, *i.e.*, an 1-(2-methylpropyl)-1H-imidazo[4,5-c]quinolin-4-amine composition, and to recite that "imiquimod is the sole active pharmaceutical ingredient applied to the human skin wrinkle in performance of the method." As amended, claim 8 recites "a method method of visibly reducing a human skin wrinkle comprising: topically applying to the human skin wrinkle an imiquimod composition in an amount and for a period of time sufficient to visibly reduce the wrinkle, wherein imiquimod is the sole active pharmaceutical ingredient applied to the human skin wrinkle in performance of the method." Support for the amendments to claim 8 can be found in the specification (*see*, *e.g.*, paragraphs [0025] and [0046] of U.S. Application Publication No. 2004/0180919), in Examples 1-3 and in the claims as originally filed. In addition to amending claim 8, new claims 33-43 have been added. Support for new claims 33-43 can also be found in the in the specification (*see*, *e.g.*, paragraphs [0038], [0050], [0052], [0053] and [0054] of U.S. Application Publication No. 2004/0180919), in Examples 1-4 and in the claims as originally filed.

Accordingly, no new matter has been introduced by the amendments to claim 8 or by the addition of new claims 33-43. Reconsideration is respectfully requested.

Rejection under 35 U.S.C. §112, First Paragraph

In the Office Action, claim 8 was rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

In an earnest effort to expedite prosecution and without acquiescing on the merits of the rejection, Applicants have amended claim 8 to recite an imiquimod composition, *i.e.*, an 1-(2-methylpropyl)-1H-imidazo[4,5-c]quinolin-4-amine composition, and to recite that imiquimod is the sole active pharmaceutical ingredient applied to the human skin wrinkle in performance of the method. Applicants respectfully submit that the specification provides more than ample written description for claim 8 as currently pending (*see*, *e.g.*, Examples 1-3 of the specification).

Accordingly, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. §112, first paragraph.

Rejection under 35 U.S.C. §103(a)

In the Office Action, claim 8 was also rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Yu *et al.*, U.S. Patent No. 6,335,023 ("Yu"), in view of Maibach, U.S. Patent Publication No. 2003/0072724 ("Maibach"). For the reasons set forth below, this rejection is overcome.

In support of this rejection, the Office Action states: "Yu et al. teaches a method of treating cosmetic conditions or dermatoligical [sic] disorders" by "topically applying a topically acceptable vehicle, at least one oligosaccharide aldonic acid, and a cosmetic, pharmaceutical or topical agent such as imiquimod." *See*, page 5 of the Office Action. However, the Office Action acknowledges that Yu "does not specifically teach applying imiquimod to treat of [sic] wrinkles." *See*, page 6 of the Office Action.

The Office Action cites Maibach as teaching the treatment of skin hyperpigmentation, and that active agents include "any compound that effectively treats warts such as imiquimod." *See*, *id.* Based on these teachings, the Office Action concludes that it would have been obvious "to combine the method of Yu et al. and applying imiquimod to treat of [sic] wrinkles." *See*, page 7 of the Office Action. Applicants disagree.

As the Office Action acknowledges, Yu does not specifically teach applying imiquimod to treat wrinkles. In fact, a review of Yu reveals that it teaches that oligosaccharide aldonic acids provide numerous benefits in the treatment and prevention of various cosmetic conditions and dermatological disorders, and that certain compounds can be administered ***in combination with*** oligosaccharide aldonic acids to treat certain cosmetic conditions and dermatological disorders. Thus, Yu does **not** teach or suggest the method of claim 8, which is directed to a method of visibly reducing a human skin wrinkle comprising: topically applying to the human skin wrinkle an imiquimod composition in an amount and for a period of time sufficient to visibly reduce the wrinkle, wherein imiquimod is the sole active pharmaceutical ingredient applied to the human skin wrinkle in performance of the method.

Maibach does **not** remedy the deficiencies of Yu. At most, Maibach teaches that imiquimod is a compound that is effective for the treatment of warts (*see*, paragraph [0092] of Maibach). Maibach does **not** teach that imiquimod, or any other compound, can be topically administered to visibly reduce a human skin wrinkle.

As such, Applicants submit that one of ordinary skill in the art would not have been motivated to combine the teachings of Yu and Maibach as suggested by the Office Action, and would not have had a reasonable expectation of success in making such a combination. Moreover, even if such a combination were made, as proposed by the Office Action, the resulting method would at best require topical treatment with a combination of Yu's oligosaccharide aldonic acids **and** imiquimod, in contrast to the claimed method of visibly reducing a human skin wrinkle visibly reducing a human skin wrinkle by topically applying to the human skin wrinkle an imiquimod composition in an amount and for a period of time sufficient to visibly reduce the wrinkle, wherein imiquimod is the sole active pharmaceutical ingredient applied to the human skin wrinkle in performance of the method. Thus, the combination of Yu and Maibach **fails** to teach or suggest the presently-claimed methods, and cannot render the present claims unpatentable.

Accordingly, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. §103(a).

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Further, the Commissioner is hereby authorized to charge any additional fees or credit any overpayment in connection with this paper to Deposit Account No. 20-1430.

Respectfully submitted,

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